

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)
_____)

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:)
)
Suits Naming Specialty Surgery Center,)
Crossville, PLLC)
)

[PROPOSED] REPLY OF SSC DEFENDANTS IN SUPPORT OF

**MOTION FOR SUGGESTION OF REMAND OF SSC CASES TO TENNESSEE
AND TO ESTABLISH VENUE IN TENNESSEE VIA §157(B)(5) OR §1404(A)**

Defendants Specialty Surgery Center, Crossville, PLLC ("SSC"), Kenneth R. Lister, MD ("Dr. Lister"), and Kenneth Lister, MD, PC ("Dr. Lister's Practice") (collectively, the "SSC Defendants") move at Dkt. 2939 to, at the conclusion of common expert discovery, remand the cases against SSC to the Middle District of Tennessee, consistent with the directive of 28 USC §1407. The Motion requests that, following remand under §1407, the Court either (1) refrain from acting on venue so as to allow the cases to proceed to trial in Tennessee; (2) set venue in Tennessee pursuant 28 USC §157(b)(5); or (3) set venue in Massachusetts pursuant §157(b)(5) and then transfer the cases to Tennessee pursuant 28 USC §1404.

Following this course (along any of the three paths) results in the most proper outcome: The Court would discharge its statutory duty under §1407 by remand of the cases to Tennessee at the logical juncture; and, following that, the cases would be tried in the appropriate venue (Tennessee) for the trial of the cases.

1. Introduction

The PSC's response, at Dkt. 2969, mistakenly characterizes the SSC Defendants' request as already decided. It has not been decided already. Further, even if the Court has generally addressed preliminary venue issues in a previous order largely specific to the STOPNC cases (Dkt. 2309), the Court certainly has not set venue for the SSC cases, nor has it done the requisite case-specific, individualized analysis of venue for the SSC cases. Undertaking the case-specific, individualized analysis for the SSC cases establishes that the appropriate venue is Tennessee.

The Court must also consider the overall landscape of the MDL. The Court plans to remand the four dozen cases against Premier, which are at the same procedural juncture as the SSC cases, and fall in the same docket, but will hold onto the two dozen SSC cases. There is no meaningful distinction between the two sets of cases, procedurally or legally. Their distinct treatment is instead based entirely on the desire of the plaintiffs' lawyers.

The fact that the Court *can* set venue in Massachusetts for the SSC cases does not mean the Court *should*. Individualized application of the factors for setting venue to the SSC cases clearly reveals the proper conclusion. The Court should follow the roadmap set out by the SSC Defendants at Dkt. 2939 and send these cases home to Tennessee after completing common discovery.

2. Reply

a. The Court has not analyzed or ruled on the proper time to remand the SSC cases or on the proper venue.

i. The PSC (again) conflates jurisdiction and venue; the Court has not analyzed venue specific to the SSC cases.

On the first page of its response, the PSC states: “The Court’s jurisdiction under § 157(b)(5) is settled. The Court has previously addressed this issue...establishing its jurisdiction under § 157(b)(5).”¹ This misstates the law and necessitates a subtle, but very important, reminder: Section 157(b)(5) is a venue statute, not a jurisdiction-conferring statute.² These are two very different principles.

Subject-matter jurisdiction defines a court’s “power to adjudicate,” while venue specifies “where judicial authority may be exercised” based on “convenience” to the “litigants.” The former asks “whether” – whether “the Legislature [has] empowered the court to hear cases of a certain genre?” The latter asks “where” – where should certain kinds of cases proceed?³

Jurisdiction establishes the power to adjudicate; venue calls on the court to determine the most convenient place for the litigants to litigate.⁴ “[S]imply because a court has jurisdiction over a case does not mean that it is the proper venue for the case to be heard.”⁵

The Court found at Dkt. 2309, after establishing that it had jurisdiction over the cases “related to” the bankruptcy, that it “will not set venue for the bellwether cases before the cases are identified.”⁶ Dkt. 2309 rules on subject matter jurisdiction over the

¹ Dkt. 2969, p. 1.

² *Stern v. Marshall*, 131 S.Ct. 2594, 2606-07 (2011).

³ *Brentwood at Hobart v. NLRB*, 675 F.3d 999, 1002 (6th Cir. 2012) (internal cites omitted).

⁴ *Still v. Rossville Crushed Stone Co.*, 370 F.2d 324, 325 (6th Cir. 1966).

⁵ *In re Harnischfeger Indus., Inc.*, 246 B.R. 421, 432 (Bank. N.D. Ala. 2000).

⁶ Dkt. 2309, p. 22 (emphasis added).

SSC cases; it did not set venue for the SSC cases, a different question that the PSC improperly lumps in with jurisdiction.

ii. To set venue, the Court must do an individualized, case-by-case analysis of the most convenient venue for the SSC cases.

A request to set venue under the doctrine of *forum non conveniens* – codified at 28 USC §1404(a) – calls for an individualized, case-by-case consideration of convenience and fairness.⁷ The Supreme Court has long held that §1404(a) requires this individualized analysis.⁸ When deciding the proper venue, the district court must employ a factually analytical, case-by-case determination of convenience and fairness⁹ and must balance the factors in a case-specific analysis¹⁰.

The obvious thrust of the case law is that, when deciding on venue, the Court must perform a case-specific and individualized factual inquiry, matching the particular facts of the case to the factors. Dkt. 2309 made brief mention of a few factors in forecasting a venue determination.¹¹ But, the Court has not – not at Dkt. 2309 or any other time – done an individualized analysis for the SSC cases, to select the most proper venue “to avoid the waste of time, energy, and money to safeguard litigants, witnesses and the public against inconvenience and expense.”^{12 13}

⁷ *Jones v. GNC Franchising, Inc.*, 211 F.3d 495, 498 (9th Cir. 2000).

⁸ *In re Genentech, Inc.*, 566 F.3d 1338, 1346 (Fed. Cir. 2009) (citing *Van Dusen v. Barrack*, 84 S.Ct. 805 (1964); *Stewart Org., Inc. v. Ricoh Corp.*, 108 S.Ct. 2239 (1988)).

⁹ *SEC v. Savoy Indus., Inc.*, 587 F.2d 1149, 1154 (D.C. Cir. 1978).

¹⁰ *Arroyo-Perez v. Demir Group Intern.*, 733 F.Supp.2d 314, 319 (D. P.R. 2010).

¹¹ Dkt. 2309, p. 22-24.

¹² *Paterson v. Wal-Mart Stores, Inc.*, No. 05-1049-CV-W-SOW, 2005 WL 3302367, at *1 (W.D. Mo. 2005).

¹³ The section 1404 factors are identified at p. 13 of the SSC Defendants’ underlying Motion, and analyzed at p. 14-20 of the Motion. (Dkt. 2940) This is the *only* time the factors have been applied thoroughly, one-by-one, to the SSC cases.

- b. The PSC apparently contends the order at Dkt. 2309 has already closed the door on the question of venue; however, the PSC is wrong, because the general, preliminary analysis at Dkt. 2309 is neither individualized nor consistent with the SSC cases.

The PSC seems to assert that the Court's mention of setting venue, and brief general statements at Dkt. 2309 regarding the proper venue for this MDL's cases, forecloses the otherwise required individualized venue analysis for the SSC cases.¹⁴ As explained above, the Court has yet to conduct the required case-specific factual inquiry for the SSC cases. Regardless, the Court's findings at Dkt. 2309 do not support a finding of venue in Massachusetts for the SSC cases.

- i. ***A.H. Robins* and *In re Dow Corning* – relied upon by the Court at Dkt. 2309 – do not fit the SSC cases.**

At Dkt. 2309, the Court cited two "similar" cases for support when invoking §157(b)(5). Neither, however, is similar to the SSC cases. In fact, when considered in the context of the true intent of §157(b)(5) – to "centralize the administration of the bankruptcy estate"¹⁵ – neither is instructive for the SSC cases.

A.H. Robins involved 5,000 product liability cases related to the Dalkon Shield intrauterine device.¹⁶ Thousands more were expected.¹⁷ The manufacturer bankrupted and reorganized.¹⁸ The court considered the propriety of centralizing all tort claims against the debtor in one place under §157(b)(5).¹⁹

¹⁴ See Dkt. 2969, p. 1-2 ("The Specialty Surgery Center Defendants have already requested these cases be tried in Tennessee, and the Court has already rejected these arguments....Most relevant to the present motion is the Court's 26-page October 7, 2015 order (the "Venue Order") which provided key background on this litigation, thoroughly examined the best venue for trying cases, and ultimately concluded that trials in Massachusetts are warranted").

¹⁵ *A.H. Robins Co. v. Piccinin*, 788 F.2d 994, 1011 (4th Cir. 1986) (additional cites omitted).

¹⁶ *Id.* at 1012.

¹⁷ *Id.*

¹⁸ *Id.* at 996.

¹⁹ *Id.* at 1011-16.

The *A.H. Robins* court endorsed centralized venue, citing the following aims of §157(b)(5): (1) to help achieve a fair reorganization of the debtor; (2) to avoid consuming “the energies of the debtor’s executives and officers...and the resources of the debtor [with] the expenses of litigating [and] the trial of thousands of personal injury suits in courts throughout the land spread over an interminable period of time”; and (3) to “harmonize” the interests of all claimants by considering claims together.²⁰

None of these considerations appears in the SSC cases: (1) NECC has not been reorganized; the plan is approved and bar date for claims passed. Thus, centralization will not assist reorganization. (2) The Court has denied the opportunity to depose an NECC representative,²¹ and document discovery of NECC has closed²². NECC is not a defendant in any SSC lawsuit and will not participate at all in Tennessee trials of the SSC cases. NECC will expend zero resources for the Tennessee trials. (3) Keeping the SSC cases in Massachusetts have no impact on the Tort Trust allocation process already underway.

The SSC cases – two dozen – are a far cry from the thousands and thousands that, if litigated in jurisdictions across the country, would have consumed the assets of the reorganizing debtor in *A.H. Robins*. The situation in *A.H. Robins* does not compare favorably to the situation here, particularly in the number of claims or – most importantly given §157(b)(5)’s true purpose – in the positive impact of centralization on the debtor. There is no meaningful impact of centralization on the debtor here, far from *A.H. Robins*, where centralization significantly helped reorganization.

²⁰ *Id.*

²¹ Dkt. 2123.

²² See Dkt. 2075, p. 3, n. 3.

Likewise, reliance on *In re Dow Corning* does not fit the SSC cases. The court there (like in *A.H. Robins*) made a venue determination to effectuate §157(b)(5)'s purpose – to centralize the administration of the estate.²³ Specifically, the Court centralized venue to increase the odds of creating a reasonable plan of reorganization, to help rehab the debtor, and to assure fair resolution of claims against the debtor.²⁴

The *In re Dow Corning* court wrote: “The question for our consideration is whether Section 157(b)(5) allows for the transfer of personal injury and wrongful death claims pending against nondebtor defendants who have been sued with a debtor under claims of joint and several liability.”²⁵ The court found that §157(b)(5) “should be read to allow a district court to fix venue for cases pending against nondebtor defendants which are ‘related to’ a debtor’s bankruptcy proceedings[.]”²⁶

However, it is important to note that the *In re Dow Corning* court did so (1) in response to a question about claims against nondebtors for joint and several liability, with the debtor a co-defendant, and (2) in order to further the goal of the section, to “centraliz[e] the administration of the bankruptcy estate.”^{27 28}

The SSC cases have virtually nothing in common with the hundreds of thousands of breast implant cases against the debtor and its affiliates in *In re Dow Corning*. The SSC cases do not even name the debtor, much less require centralization to help administer the (already-confirmed) bankruptcy plan of a (defunct and unrelated) entity. *In re Dow Corning* does not justify the use of §157(b)(5) in the very different SSC cases.

²³ *In re Dow Corning*, 86 F.3d 482, 496 (6th Cir. 1996).

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.* at 497.

²⁷ *Id.*

²⁸ Of note, it also did not do an abstention analysis for the claims against the nondebtors. *Id.* at 497-98.

* * * * *

There are two core points to draw from application of *A.H. Robins* and *In re Dow Corning* to the SSC cases: First, neither fits the circumstance of the SSC cases, primarily because trial of the SSC cases in Tennessee will not threaten to consume the assets and resources of the debtor. In fact, trial of the SSC cases in Tennessee will consume none of the assets of the debtor; the debtor will not even participate in the SSC cases.²⁹ Second, trying the cases in Tennessee instead of Massachusetts in no way improves the reorganization or rehabilitation of NECC. There is no reorganization. Trying the SSC cases in Massachusetts does not positively impact the execution of the bankruptcy plan at all, which was the decisive point behind centralization in *A.H. Robins* and *In re Dow Corning*.

ii. The reasons for trial in Massachusetts mentioned at Dkt. 2309 do not apply to the SSC cases.

The Court did do a cursory analysis of the venue question at Dkt. 2309, although not specific to the SSC cases.³⁰ While some of the analysis may apply generically to this MDL, the analysis does not work when the Court takes an individualized look at the SSC cases.

²⁹ The notion that trying the cases in Massachusetts rather than Tennessee is somehow easier on the debtor is an illusion. Trial in either location requires no debtor participation. Discovery of the debtor is over. In fact, trying the case in Tennessee likely imposes less cost on the debtor than in Massachusetts. First, if the case is tried in Massachusetts, the debtor will have to file (through the post-confirmation officer) a motion to set venue in Massachusetts. That will require briefing and argument, a cost to the estate. Then, in Massachusetts, the debtor (and its officers and employees) will be subject to trial subpoenas. If the case is tried in Tennessee, the proof of the debtor's acts will be documentary, and the debtor and its officers and employees remain outside the court's subpoena power, incurring no cost. In neither case will the debtor have a judgment against it.

³⁰ Dkt. 2309, p. 22-24.

At Dkt. 2309, the Court cited three general reasons why venue in Massachusetts made sense:

1. Much of the evidence in this MDL – which is largely documentary – is in Massachusetts. Where it is not, the witnesses can testify by video or video-link.^{31 32}
2. The Court is familiar with the docket.³³
3. A plurality of the lawyers in the MDL are from Massachusetts.³⁴

None of these justifies setting venue for the SSC cases in Massachusetts.

First, the Court properly makes a distinction at Dkt. 2309 between the location of documentary evidence (not that important to the convenience analysis because it is easily moved) and live witnesses (important in the analysis because they will have to travel if venue is not their home state).

However, when applied to the SSC cases, the Court reaches the wrong conclusion. The documentary evidence in the SSC cases is largely related to comparative fault and is housed online. The fact that some remaining original documents may be located in Massachusetts is inconsequential to the overall analysis.

But, the important live evidence in the SSC cases is located largely in Tennessee. The testimony of Massachusetts witnesses the Court allowed the SSC Defendants to depose has already been captured by video. So, reason one cited at Dkt. 2309, applied to the SSC cases, weighs not toward trial in Massachusetts, but toward trial in Tennessee. The fact that some original documents “reside” in Massachusetts

³¹ Dkt. 2309, p. 23.

³² Common sense must prevail here. No reasonable court or counsel would say that a trial consisting of evidence presented largely by documents and videotaped testimony, presented to a jury in a locale far away from the nexus of facts, is a more effective search for the truth than trying the case with live witnesses to a local jury with a true interest in the case.

³³ Dkt. 2309, p. 23.

³⁴ Dkt. 2309, p. 23-24.

does not justify requiring the parties and a half-dozen or more fact witnesses and a dozen experts to travel from Tennessee to Massachusetts for trial.

Second, the SSC Defendants do not dispute that the Court is familiar with the MDL. But, the Court did not mention an important SSC-specific factor: The vast, vast majority of the docket entries have no importance to the SSC trials; they instead deal with issues like the bankruptcy, jurisdiction, discovery of NECC, and cases in other states.³⁵ The Tennessee court will not have to review all the docket entries. Only a handful are specific to the SSC cases, and the parties can easily identify those for the Tennessee court.

Also, because the Dkt. 2309 analysis was not an SSC-specific, individualized analysis, the Court made no mention of the pending declaratory judgment action in the Middle District of Tennessee. Through that declaratory judgment action, the Middle District of Tennessee (1) has already set up a leadership structure for the SSC Plaintiffs³⁶; (2) held hearings on the declaratory judgment action; (3) issued rulings on the declaratory judgment action; and (4) issued orders that reflect an understanding of the factual background, procedural history, and legal underpinning of the SSC cases in the MDL³⁷. Put simply, the Middle District of Tennessee is also familiar with the cases.

In the PSC's response to the underlying motion, it argues that the Court's familiarity with the MDL warranted continuing in Massachusetts because the Court

³⁵ The MDL structure is set up such that cases are returned after pretrial discovery for trial, anyway. In *all* MDL cases that return to the home district for trial, the MDL court will be more familiar with the docket.

³⁶ See order attached as exhibit 1.

³⁷ See order attached as exhibit 2.

moved the STOPNC cases to trial “faster than in any other jurisdiction” and the Tennessee judge would have to develop a bellwether protocol from scratch.³⁸

However, we know that Massachusetts is not the only jurisdiction that can achieve a timely trial date – one case has already been tried in Michigan. And, the Middle District of Tennessee set the declaratory judgment action related to these tort cases for trial in November of this year. There is no legitimate showing that a Tennessee court cannot try these cases in a reasonable timeframe.

Lastly, PSC’s statement that a Tennessee court would have to create a bellwether protocol from scratch is wrong. Why the Tennessee court would have to reinvent the entire bellwether process from scratch is not explained by the PSC. The parties mostly negotiated the bellwether protocol and would likely largely agree on the protocol again. What is not agreed upon can be easily remedied by the district court.

Third, the Court’s statement about a plurality of the lawyers being stationed in Massachusetts is inaccurate, particularly when applied to the SSC cases. The only lawyers active in litigating the SSC cases on the Plaintiffs’ end are from Tennessee. In fact, a Massachusetts lawyer filed only one of the 24 SSC cases. The lawyers who will try the SSC cases are virtually all from Tennessee. The bottom line is that, as it relates to the SSC cases, the Court’s statement that the plurality of lawyers are from Massachusetts inaccurate.³⁹

* * * * *

³⁸ Dkt. 2969, p. 4-5.

³⁹ Setting this aside, the Court should consider the convenience to the litigants and witnesses, not the lawyers. Interestingly, plaintiffs’ lawyers in this MDL advocate that Boston is the most convenient forum to try the case; yet, repeatedly, the Court entertains requests to appear by telephone from the same lawyers because of the travel burden. *Compare* Dkt. 2935, Hr’g Tr. 44-47 (6/22/16 status conference), *with* Dkts. 2970, 2972. And, the PSC, now advocating for the convenience of a multi-week trial in Boston, was the group that first advocated for the option of calling into status conferences by phone to ease the travel burden. Dkt. 970.

Respectfully, the general analysis done at Dkt. 2309 does not supplant the required case-specific SSC venue analysis. It most certainly does not demonstrate that venue in Massachusetts is proper for the SSC cases. The Dkt. 2309 preliminary analysis, stretched to cover the SSC cases, actually points the opposite direction. Adding in the full analysis only serves to drive the point home.

4. Conclusion

There is no good reason that the Court must search for a thread connecting the SSC cases to the bankruptcy, strain to find an opening to invoke §157(b)(5), and then ignore the overwhelming weight of evidence favoring trial in Tennessee over trial in Massachusetts. The proper case-specific, individualized §157(b)(5)/§1404 analysis for the SSC cases has not occurred. When it does, in conjunction with the SSC Defendants' underlying motion, the Court must reach the logical conclusion: "Consolidation" of the cases in Massachusetts does nothing for the bankruptcy. On the other hand, trial of the SSC cases in Tennessee is by far the most convenient and most fair for the litigants and witnesses.

Respectfully submitted,

/s/ Kent E. Krause

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Attorneys for the SSC Defendants

*Admitted pursuant to MDL Order No. 1

**Admitted pro hac vice

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be served via electronic mail or regular U.S. mail to those participants identified as unregistered this the ____ day of July, 2016.

/s/ Chris J. Tardio

CHRIS J. TARDIO

EXHIBIT 1

**[ORDER APPOINTING LEAD COUNSEL
IN DEC ACTION]**

**IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE**

STATE FARM FIRE AND CASUALTY) COMPANY,)) Plaintiff,)) v.))	CASE NO. 2:15-CV-00026
SPECIALTY SURGERY CENTER,) PLLC, et al.,)) Defendants.))	JURY TRIAL DEMANDED JUDGE SHARP/BROWN

**ORDER APPOINTING LEAD COUNSEL FOR
INDIVIDUAL TORT-VICTIM DEFENDANTS**

This order is intended to create a leadership structure for the Individual Tort Victim Defendants'¹ counsel to organize, simplify, and streamline the handling of these matters on behalf of the Individual Tort Victim Defendants, consistent with the fair administration of justice.

1. LEAD COUNSEL

The Court hereby appoints the following as Lead Counsel for the Individual Tort Victim Defendants:

J. Gerard Stranch, IV
(with Benjamin A. Gastel as his alternate)
BRANSTETTER, STRANCH & JENNINGS, PLLC
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¹ The individually named Defendants, as listed on the Complaint are: Elizabeth Bray, Peggy B. Bumgarner, Roger D. Bumgarner, Lawrence Carter, Wilma S. Carter, Judy Collins, Perry Cox, Wanda J. Cox, Wanda J. Dingess, Bobby A. Foster, Dorothy A. Fuelling, Richard E. Fuelling, Danette Graham, Georgeanne Hubbard, Linda Jackson, John Johnson, Edna S. Keyes, William Lapiska, Sherry A. McDavid, Darwin L. Nealon, Jocelyn Kae Norris, James Palmer, Michelle Palmer, J. E. Reed, Wanda L. Reed, Christopher G. Rhind, Janice K. Rhind, Shirley Savercool, Jim F. Smith, Paula K. Smith, Craig E. Weaver, and Dale Willis.

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The responsibilities of Lead Counsel are set forth in Section 3 of this Order.

2. CHANGES IN MEMBERSHIP

These appointments are personal in nature, and may not be changed without further Order of this Court.

3. RESPONSIBILITIES OF LEAD COUNSEL

Lead Counsel shall have the following responsibilities:

- a. Generally responsible for coordinating the activities of Individual Tort Victim Defendants' counsel during pretrial proceedings;
- b. To present, after consultation with the Individual Tort Victim Defendants' counsel as may be appropriate, personally or by designee, the position of the Individual Tort Victim Defendants on any matter arising during pretrial proceedings;
- c. To delegate specific tasks to other counsel in a manner to ensure that pretrial preparation for the Individual Tort Victim Defendants is conducted effectively, efficiently, and economically, including the creation of subject-matter specific or other working groups;
- d. To prepare and distribute to the parties periodic status reports, as appropriate;

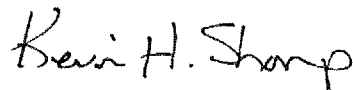
- e. To receive and distribute to the Individual Tort Victim Defendants' counsel, as appropriate, orders, notices and correspondence from the Court and opposing counsel; and
- f. To maintain and make available to other Individual Tort Victim Defendants' counsel, on reasonable notice and at reasonable times, a complete set of all pleadings and orders filed and/or served in this action.

Lead Counsel shall be involved in any class or group settlement discussions.

4. PRIVILEGED COMMUNICATIONS

Because cooperation among counsel and the parties is essential for the orderly and expeditious resolution of the litigation, the communication, transmission, or dissemination of information among Individual Tort Victim Defendants' counsel shall be subject to the joint attorney-client privilege and the protections afforded by the attorney work-product doctrine; provided, however, that the conditions necessary to create such a privilege or protection have been satisfied and the privilege or protection has not been waived.

SO ORDERED this 19th day of August, 2015.



JUDGE KEVIN H. SHARP
United States Chief District Judge

EXHIBIT 2

**[ORDER CERTIFYING
PRODUCT LIABILITY QUESTION
IN DEC ACTION]**

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
AT NASHVILLE

STATE FARM FIRE AND CASUALTY)
COMPANY,)
)
Plaintiff,)
)
v.)
)
SPECIALTY SURGERY CENTER, PLLC,)
KENNETH R. LISTER, M.D., ELIZABETH)
BRAY, PEGGY B. BUMGARNER, ROGER)
D. BUMGARNER, WILMA S. CARTER,)
LAWRENCE CARTER, JUDY COLLINS,)
WANDA J. COX, PERRY COX, WANDA)
J. DINGESS, BOBBY A. FOSTER,)
DOROTHY A. FUELLING, RICHARD E.)
FUELLING, CRAIG E. WEAVER,)
Administrator Ad Litem of the Estate of)
PATRICIA A. GAMBACCINI, DANETTE)
GRAHAM, GEORGEANNE HUBBARD,)
LINDA JACKSON, JOHN JOHNSON, EDNA)
S. KEYES, WILLIAM LAPISKA, SHERRY A.)
MCDAVID, next of kin of DONALD F.)
MCDAVID, DARWIN L. NEALON,)
Administrator of the Estate of DALLAS RAY)
NEALON, JOCELYN KAE NORRIS, JAMES)
PALMER, MICHELLE PALMER, WANDA)
L. REED, J.E. REED, JANICE K. RHIND,)
CHRISTOPHER G. RHIND, SHIRLEY)
SAVERCOOL, PAULA K. SMITH, JIM F.)
SMITH, and DALE WILLIS,)
)
Defendants.)

Case No. 2:15-cv-00026

Chief Dist. Judge Kevin Sharp

Magistrate Judge Joe Brown

ORDER CERTIFYING QUESTIONS OF LAW TO TENNESSEE SUPREME COURT
UNDER TENNESSEE SUPREME COURT RULE 23

The United States District Court for the Middle District of Tennessee certifies the following questions to the Supreme Court of Tennessee under Tennessee Supreme Court Rule 23.

(A) The style of the case

The style of the case is in the caption of this Order.

(B) A statement of facts showing the nature of the case, the circumstances out of which the questions of law arise, the questions of law to be answered, and any other information the certifying court deems relevant to the questions of law to be answered.

1. Nature of the case

General background

The unresolved Tennessee state law issues for the Tennessee Supreme Court's consideration arise from claims asserted in underlying tort litigation related to the 2012 fungal meningitis outbreak. In this declaratory judgment action, the Insurer (State Farm) sues the Insureds (Specialty Surgery Center, PLLC and Kenneth Lister, MD) and former patients ("Individual Tort Victim Defendants" or "ITV Defendants"). The Insurer seeks a declaration that it does not owe the Insureds a defense or indemnity coverage in the tort suits brought by the ITV Defendants against the Insureds.

The ITV Defendants are former patients of the Insured health care providers asserting injuries from the 2012 fungal meningitis outbreak. These lawsuits, along with scores of others against health care providers around the country, have been consolidated in multi-district litigation in the United States District Court for the District of Massachusetts.¹ One of the claims the ITV Defendants make against Dr. Lister and Specialty Surgery Center (“SSC”) in the underlying tort suits is that the Insured health care providers are strictly liable under Tennessee’s Product Liability Act, Tennessee Code Annotated § 29-28-101, *et seq.*, as “sellers” of contaminated medication furnished to the ITV Defendants as a component of health care services.

Insurer’s position in declaratory judgment action

State Farm’s position is two-fold: First, the ITV Defendants cannot, as a matter of law, maintain a cause of action for product liability against SSC or Dr. Lister related to the outbreak. Second, if the Court rules that the product liability claim is not viable as a matter of law, the only remaining viable claims against SSC and Dr. Lister in the underlying tort suits are for professional health care liability, specifically excluded from coverage under the applicable insurance policy.²

State Farm requests that the Middle District of Tennessee declare that (1) the ITV Defendants cannot, as a matter of law, pursue a claim of strict product liability against the Insureds arising from the fungal meningitis outbreak; and (2) because the product liability claim is not legally viable, State Farm has no duty to provide a defense or indemnity coverage to the Insureds.

¹ U.S. District Court, Massachusetts, MDL No. 2419 // Dkt. No 1:13-md-2419 (RWZ).

² This coverage suit hinges on the viability of the ITV Defendants’ product liability claim against SSC and Dr. Lister. If it is not viable, State Farm’s policy does not cover the claims.

2. Circumstances out of which the questions of law arise

In the summer 2012, New England Compounding Center (“NECC”) – a compounding pharmacy in Massachusetts – produced three batches of preservative-free methylprednisolone acetate (“MPA”). During production, the MPA was contaminated with a fungus. NECC shipped contaminated vials to health care providers across the country, including three (3) clinics in Tennessee, one of which was SSC.

Dr. Lister and other physicians across the country injected the MPA supplied by NECC in individual, sealed vials, during procedures known as epidural steroid injections (“ESIs”), unaware that the MPA was contaminated. Hundreds of patients in multiple states filed suit. Twenty-four (24) lawsuits were filed against SSC and Dr. Lister. All the federal fungal meningitis lawsuits, including those against SSC and Dr. Lister, have been consolidated for pretrial proceedings in multi-district litigation pending in the U.S. District Court for the District of Massachusetts.

NECC (the manufacturer of the medicine) filed a petition in bankruptcy in U.S. Bankruptcy Court on December 21, 2012. The Tennessee Product Liability Act of 1978 permits plaintiffs to pursue a claim for strict liability in tort against the seller in the chain of distribution of a good in only limited circumstances, including when the manufacturer is bankrupt.³ In the underlying complaints against SSC and Dr. Lister, the ITV Defendants assert that SSC and Dr. Lister acted as “sellers” of the MPA for purposes of the Tennessee Product Liability Act when Dr. Lister injected the medicine into the ITV Defendants in 2012.⁴ SSC and Dr. Lister dispute that they “sold” the medication and

³ TENN. CODE ANN. §§ 29-28-102, -106.

⁴ SSC and Dr. Lister moved to dismiss the product claims. The Massachusetts District Court denied the motion but noted on several occasions that there is no Tennessee law addressing whether a health care provider can be considered a seller of medication used incidental to health care services, exposing the

instead assert they used it only incidental to the delivery of professional health care services.

State Farm issued a commercial liability policy and a commercial liability umbrella policy to SSC and Dr. Lister that were in effect at the time of the injections in 2012. The parties agree that there is no specific exclusion in State Farm's policy for claims grounded in "strict product liability" against SSC and Dr. Lister. However, State Farm asserts that the product liability claim is not viable as a matter of law, and, if the product liability claim in the underlying complaints is not viable, State Farm should not be obligated to provide a defense and coverage.⁵

State Farm and the Insured health care providers aver that the ITV Defendants cannot maintain a strict product liability cause of action for two (2) principal reasons. First, they assert that the claims against the Insureds are health care liability actions governed by Tennessee's Health Care Liability Act ("HCLA")⁶, which is the ITV Defendants' exclusive substantive remedy on these facts. Second, they assert that SSC was not acting as a "seller" under Tennessee's Product Liability Act.⁷

health care provider to strict product liability. See Order on Global Motion to Dismiss, August 29, 2014, 2014 WL 4322409, at *14-*15 ("The Tennessee Clinic Defendants acknowledge that Tennessee has not specifically addressed whether health care providers can be held strictly liable as sellers...This court's case law research did not unearth any Tennessee cases in which products liability claims were successfully brought against health care providers, nor any cases indicating that health care providers were categorically not sellers or could not be sued under the [Tennessee Product Liability Act]....As of the date of this opinion, there are no cases dealing with the interaction of products liability claims with the [Tennessee Health Care Liability Act]").

⁵ An answer on the issue of the viability of the product liability claim will resolve all (or virtually all) of the issues in the declaratory judgment action in front of this Court. In the MDL, the Intervenor Plaintiffs (Plaintiffs with suits against another Tennessee clinic who purchased and administered MPA from NECC, Saint Thomas Outpatient Neurosurgical Center, LLC) have moved for summary judgment on the same issue. Thus, in addition to resolving the issues in the declaratory judgment action, answering this question will likely resolve the same issue in the MDL.

⁶ TENN. CODE ANN. § 29-26-101, *et seq.*

⁷ TENN. CODE ANN. § 29-28-101, *et seq.*

3. Operative undisputed facts

The following material facts are undisputed for purposes of deciding these legal questions:

1. This declaratory judgment action follows tort lawsuits arising from the 2012 outbreak of fungal meningitis and fungal infection caused by three (3) batches of preservative-free methylprednisolone acetate compounded and sold by NECC from May 2012 through September 2012.

2. NECC was a compounding pharmacy located in Massachusetts. It was licensed as a pharmacy in Massachusetts, in Tennessee pursuant to Title 63 of the Tennessee Code, and in every other state in the union.

3. MPA is a steroid commonly used to treat chronic back or neck pain. During an epidural steroid injection, the MPA is injected into the epidural space with x-ray guidance. The medication reduces swelling and inflammation of the nerves and tissue surrounding the spine, relieving pain.

4. In 2012, SSC was an accredited ambulatory surgery center in Crossville, Tennessee, licensed pursuant to Title 68 of the Tennessee Code.⁸

5. Dr. Lister is an anesthesiologist licensed pursuant to Title 63 of the Tennessee Code. He was a member of SSC in 2012.

6. The ITV Defendants sought treatment for back and neck pain from SSC and Dr. Lister.

7. SSC procured MPA from NECC for Dr. Lister to use at SSC when treating patients.

8. SSC began purchasing MPA from NECC in July 2012 after Dr. Lister became concerned about possible adverse patient reactions from preservatives present in the brand-name version of the medication, "Depo Medrol," available commercially from Pfizer. SSC's Director of Nursing, Jean Atkinson, RN, in consultation with Dr. Lister and SSC's management company, made the decision to purchase a preservative-free formulation of MPA from NECC.

9. SSC paid NECC \$8.00 per one milliliter vial of MPA. Dr. Lister administered one vial of MPA to a patient during an epidural steroid injection.

10. Dr. Lister performed epidural steroid injections on the ITV Defendants to treat their back and neck pain. The steroid administered during the ITV Defendants' procedures was preservative-free MPA compounded by NECC.

⁸ SSC is no longer operating.

11. Two fees were charged for the epidural steroid injections: a physician fee by Dr. Lister, and a facility fee by SSC.

12. Dr. Lister charged the ITV Defendants and/or their insurers the physician fee for his professional services during the epidural steroid injection procedures.

13. SSC charged the ITV Defendants and/or their insurers a facility fee of \$1,250, which was a single, global fee for the epidural steroid injections that covered all aspects of the injection. This included:

a. The professional services of a nurse to assist Dr. Lister in performing the procedure, including administering a sedative when necessary⁹;

b. The professional services of a surgical technician to assist Dr. Lister in performing the procedure, including positioning the fluoroscopy (x-ray) machine used to provide Dr. Lister with real-time images of the patient's spine during the procedure to ensure the MPA was being injected into the epidural space;

c. Use of SSC's facility, including an operating room for the procedure and a post-procedure recovery room;

d. Use of SSC's medical equipment, including the fluoroscopy machine used during the procedure and the equipment used to monitor the ITV Defendants' vital signs during the procedure;

e. The medications administered during the procedure, including, but not limited to, MPA from NECC;

f. The medical supplies used during the procedures, such as latex gloves, surgical masks, and gowns; and,

g. Administrative services such as recordkeeping, billing, and scheduling.

14. SSC was reimbursed approximately \$200-\$300 for the ITV Defendants' procedures.¹⁰

15. The majority of the ITV Defendants are Medicare beneficiaries.

16. Neither SSC nor Dr. Lister billed the ITV Defendants or their insurers separately for the MPA administered during their procedures.

⁹ Some patients chose not to be sedated because they wanted to be able to drive home after the procedure and could not do so if they had been sedated.

¹⁰ The reimbursement varied to some extent depending on the terms of the contract between SSC and the patient's insurer.

17. SSC and Dr. Lister did not collect sales tax from the ITV Defendants or their insurers for the MPA administered during the procedures.

18. The steroid administered to the ITV Defendants was later found to have been contaminated during compounding by NECC.

19. The ITV Defendants allege that the steroid caused varying degrees of injury and, in some cases, death.

20. NECC sought bankruptcy protection on December 21, 2012.

21. After NECC declared bankruptcy, the ITV Defendants filed suit against SSC and Dr. Lister alleging, among other things, that they are strictly liable as “sellers” of the MPA administered to the ITV Defendants, under Tenn. Code Ann. § 29-28-106.

22. NECC’s bankruptcy plan was confirmed on May 20, 2015. The plan includes a settlement fund of approximately \$200 million for the benefit of the victims of NECC’s wrongdoing. The lawsuits against various clinics continue, including those against SSC and Dr. Lister.

4. Questions of law to be answered

The District Court requests that the Tennessee Supreme Court answer the following questions:

- (1) Can a patient maintain a strict products liability action against an ambulatory surgery center licensed under Tennessee Code Title 68, or a physician licensed under Tennessee Code Title 63, for an injury sustained during an epidural steroid injection procedure, given the definition of a “health care liability action” under Tenn. Code Ann. § 29-26-101 and the burden of proof requirements established by Tenn. Code Ann. § 29-26-115?
- (2) Is an ambulatory surgery center, licensed pursuant to Tennessee Code Title 68, “engaged in the business of selling” the steroid administered during an epidural steroid injection procedure, so as to be strictly liable as a “seller” under Tenn. Code Ann. § 29-28-106?

5. Any other information the certifying court deems relevant to the questions of law to be answered

None.

(C) The names of each of the parties

The parties are identified in the style above.

(D) The names, addresses, and telephone numbers of counsel for each party

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(E) A designation of the moving parties


The Court designates the following as the moving parties:

- State Farm Fire & Casualty Company
- Specialty Surgery Center, PLLC
- Kenneth Lister, MD.¹¹

* * * * *

This honorable Court hereby certifies the above questions by this Order to the Tennessee Supreme Court and requests that the Tennessee Supreme Court consider them and answer them in due course.

Dated: June 16, 2016



**KEVIN H. SHARP
CHIEF DISTRICT JUDGE
UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE**

¹¹ Given that State Farm, SSC, and Dr. Lister's interests align on the questions presented, this Court designates them as the moving parties, and respectfully recommends that they file the opening brief(s), and that the other parties to this action file the response brief. If the Tennessee Supreme Court prefers that only one party be designated, this Court suggests that State Farm be designated as the moving party.

Jointly submitted for entry,

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